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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/431,519	11/01/99	CHUNG S	AH0948Q

HM12/0714

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PATENT DEPT K-6-1 1990
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EXAMINER	
LEVY, N	
ART UNIT	**PAPER NUMBER**
1616	4

DATE MAILED: 07/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
43579	Chung et al	
Examiner	Group Art Unit	
NBL Levy	1616	4

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Dispositi n of Claims

☒ Claim(s) 1-42 is/are pending in the application.

Of the above claim(s) 21-42 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Applicati n Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Applicant's election with traverse of Group I in Paper No. 3 is acknowledged. The traversal is on the ground(s) that 1-42 form part of one and the same invention. This is not found persuasive because examiner holds to restriction as presented.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-42 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 3.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what limitation is intended by "cooperate".

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is indeterminate as to how "cooperation" is to be effected by the formulations, and which portion thereof contributes to the cooperation means.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3 Claims 1-13,16,17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Deasy 4874612.

Polylactide-coglycolide (col 1, line 50-line 44, col 2) implants permit control of rate of release of (Zeranol, Frenbolone, col 3) actives as desired, with a number of compartments permitting a range of release rates, within the instant ratio. The active is 20-80% (col 3, top) additives may be present; hormones, anabolic; are used, sub Q, in combination (col 3) in cattle (col 4, bottom).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deasy and Porter GB 2397484 in view of Horykiewytsch et al 5252561.

Deasy, above, provides implants for cattle, of the instant anabolic agents, but does not teach the instant cellulosic rate control agent.

Porter show cattle implants of immediate release (p.2) and controlled release of beneficial agents cooperating to improve growth, by permitting fast release from one portion and sustained release from another portion of a double bolus (p.6). The diluent is lactose (Example 1) binder of cellulose or starch (Example 4). See also claims 5-8. Anabolic agents are not mentioned. Hornykiewytsch show them (cols. 1,3) for ruminants, including trenbolone, estradiol, progesterone (col.4, top). Sugar, cellulose, tableting agents (lubricant) are utilized (col 3). Sugars include lactose (col 6, lines 15-28) cellulosics include methyl cellulose, hydroxyethyl cellulose. Active agents are at up to 75%, controlled release agents 1-27% (col 3, lines 5-25). Shown also are multiple release compartment (fig.2,3). Control of profile of release in with on the skill of one in the art (col 8, lines 1-15). Porter discloses the instant inventive composition implants, suitable for ruminant application, at the instant concentrations except for use of nutrients instead of anabolic steroids. Hornykiewytsch however, teaches the instant elements, equivalent to the instant steroids but lacking in multiple release rate disclosure, in a similar format of both the instantly claimed invention and Porter and Deasy.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an immediate followed by continued release of beneficial

agent, to use that of Porter or Deasy with agents of choice for the use desired, as shown 1 col 8, Hornykiewytsch or Deasy) to include enhanced metabolism, growth and feed utilization. The various hormones/steroids are all known compounds considered, as this office takes notice, to be equivalent choices for on in the art to select, as are the binding and release agents.

The selection of adjuvant and active ingredients and concentrations are result effective parameters chosen to obtain the desired effects. It would be obvious to vary concentration and form of each ingredient to optimize the effect desired ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al 2546759.

Lee disclose substaneously implantable hormone and hormone-like active anabolic agents (col , lines 1-9, col 2, lines 10-26). Form is not critical, and excipients, diluents are used (col 4, lines 29, 55-74) including sugar, an the anabolic agent is applied as an outer layer (col 5, lines 25-30). Improvement in the art is shown by Nessel providing steroid anabolic agents for subq to cattle in a polymer matrix, compared to a lactose release agent (Table I). Here we see lactose provides quick release, polymer, sustained. Further advances are disclosed by Dunn; of biodegradable polymeric sub Q drug implants (col 1, lines 19-28) of poly D, L-lactide. Starting

(Col 3, lines 30-32) and using both polylactides) polyglycolides or mixes or copolymers, along with (col 4, lines 50- lines 3, col 5) Example 6). Drugs include steroids, androgenic agents and esters of suitable drugs, non critical (col 6, lines 55- col 7, line 8), the amount dependent on desired release profile) determinable by artisan (col 7, lines 9-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a one shot composition, to use one of Lee, modified with Nessel to provide acceptable application to cattle. Dunn teaches one having ordinary skill in the art would be motivated to perform this modification in order to prolong delivery, but permit bio degradation of the polymeric carrier.

The selection of each polymer and active ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the use of Anabolic compounds for enhancement and the use of ingredients for the functionality for which they are known to be use is not a basis for patentability.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday-Friday from 7:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Dees/sg

July 11, 2000

NEIL S. LEVY
PRIMARY EXAMINER